

U.S.S.N. 10/613,975

Filed: July 3, 2003

AMENDMENT AND RESPONSE TO OFFICE ACTION

In the Claims

1. (original) A vaccine composition for inducing an immune response to a pathogen comprising a nucleic acid encoding an antigen eliciting an immune response to the pathogen encapsulated in a mucoadhesive controlled release particulate formulation.

2. (original) The composition of claim 1 wherein the formulation comprises a biodegradable polymer.

3. (original) The composition of claim 2 further comprising a mucoadhesive polymer coating.

4. (original) The composition of claim 1 further comprising an enteric outer coating or capsule.

5. (original) The composition of claim 1 having a particulate diameter of less than five microns.

6. (original) The composition of claim 2 formed by
lyophilizing a solution of a biodegradable polymer to form an open-celled polymeric foam of approximately 95% void volume,
impregnating the foam with an aqueous solution of the nucleic acid,
lyophilizing the foam to remove the water, and
extruding the resulting matrix at ultrahigh pressures.

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7. (original) The composition of claim 2 wherein the method further comprises
cryogenically grinding the matrix to an average particle size of fifteen microns in
diameter; and
sieving to isolate particles less than five microns in diameter.
8. (original) The composition of claim 1 wherein the polymer is a low molecular weight
poly(D,L-lactide-co-glycolide).
9. (amended) The composition of claim 1 wherein the pathogen is selected from the group
consisting of malaria, tularemia, anthrax, and *H. Helicobacter pylori*.
10. (original) The composition of claim 1 further comprising providing an adjuvant with the
antigen.
11. (original) The composition of claim 1 wherein the antigen is expressed or released for a
period of weeks to months.
12. (canceled) A porous particulate formulation comprising an antigen and having a
mucoadhesive coating, wherein the formulation is suitable for administration orally or nasally.
13. (canceled) The formulation of claim 12 wherein the antigen is selected from the group
consisting of a malaria antigen, a tularemia antigen, an anthrax antigen, and a *H. pylori* antigen.
14. (canceled) The formulation of claim 12 wherein the antigen is a peptide.
15. (canceled) The formulation of claim 12 wherein the antigen is expressed from nucleic
acid incorporated into the particulate formulation.
16. (canceled) The formulation of claim 12 further comprising an adjuvant.

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17. (canceled) The formulation of claim 12 wherein the particulate has a mucoadhesive coating and a diameter of less than five microns.

18. (canceled) The formulation of claim 12 wherein the formulation is enterically coated or encapsulated within an enteric capsule.

19. (canceled) The formulation of claim 12 wherein the antigen is expressed or released for a period of weeks to months.

20. (canceled) A method of inducing an immune response to a pathogen comprising administering to a patient by an oral or nasal route a vaccine composition comprising a nucleic acid encoding an antigen eliciting an immune response to the pathogen encapsulated in a mucoadhesive controlled release particulate formulation.

21. (canceled) The method of claim 20 wherein a priming dose is administered before an immunizing dose is administered.